K023772

NOV 22 2002

510(k) Summary of Safety and Effectiveness

Acuson Corporation's *KinetDx - Medical Image Management Device*

Acuson Corporation has not disclosed its intent to market this device modification and requests this notification be held CONFIDENTIAL by FDA, and not be released to any Freedom of Information request or addressed with any outside parties.

Sponsor: Siemens Medical Solutions,
Acuson Ultrasound Division
1230 Shorebird Way
Mountain View, CA 94043

Contact Person: Bob Leiker
Senior Regulatory Affairs Specialist
Telephone: (650) 694-5080
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Submission Date: October 31, 2002

Device Name: KinetDx

Common or Usual Name: Picture Archival and Communications System

Classification:
Picture Archival and Communications System (LLZ) class II (21CFR §892.2050)

Predicate Device:
EchoLink, K980060 cleared on February 25, 1998
ALI UltraPacs, K925965 cleared on June 14, 1993
ALI DataComPacs Module, K963610, cleared on November 27, 1996

Device Description:
KinetDx is a picture archival and communications system (PACS) that includes a dedicated DICOM server used for image and data storage, retrieval, and archiving. The server accepts images and data from DICOM acquisition devices attached to it by way of a network. The system also includes one or more workstations networked with the server, which are used for clinical review of images and data. Workstations also allow editing of patient demographic and clinical data, image manipulation, and preparation of clinician's reports.

Intended Use:
The intended use of the $KinetD_x$ is for the acceptance, transfer, display, storage, and digital processing of diagnostic ultrasound, CT, MRI, and X-ray angiography images, including manipulation and quantification of the images.

Technological Characteristics and Substantial Equivalence:
Similar to the predicate devices, the computer hardware components used for the KinetDx server and review stations are standard computer hardware procured from qualified vendors, with the exception of an optional proprietary card available for review stations. This optional card, the KinetDx Dynamic Array Processor (DAP) card, provides faster decompression and display of image data than can be provided using regular system memory. The KinetDx server and review stations use proprietary software to accomplish their functions. Servers and review stations use the Windows2000 operating system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 22 2002

Acuson Corporation
% Mr. Mark Job
510(K) Program Manager
TÜV Product Service
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

Re: K023772
Trade/Device Name: KinetDx Picture Archiving and Communications System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: November 8, 2002
Received: November 12, 2002

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K023772

Indications For Use

The intended use of the KinetD$_x$ is for the acceptance, transfer, display, storage, and digital processing of diagnostic ultrasound, CT, MRI, and X-ray angiography images, including manipulation and quantification of the images.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David G. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023772